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EXAMINER

HUI, SAN MING R

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* SHOUKAT DEDHAR, GREG HANNIGAN,  
DAVID W.C. HUNT, JING-SONG TAO  
and LADAN FAZLI

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Appeal 2010-002642  
Application 09/998,250  
Technology Center 1600

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Before DONALD E. ADAMS, JEFFREY N. FREDMAN, and  
STEPHEN WALSH, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL<sup>1</sup>

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<sup>1</sup> The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the “MAIL DATE” (paper delivery mode) or the “NOTIFICATION DATE” (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

This appeal under 35 U.S.C. § 134 involves claim 1<sup>2</sup>. We have jurisdiction under 35 U.S.C. § 6(b).

#### STATEMENT OF THE CASE

Claim 1 is directed to a method for treating psoriasis and is reproduced below:

1. A method for treating psoriasis, the method comprising:  
administering an effective amount of an inhibitor of integrin linked kinase (ILK) to a psoriatic lesion, wherein expression of ILK in psoriatic tissue correlates with severity of disease, and said ILK inhibitor is a small organic molecule that inhibits ILK activity.

The rejections presented by the Examiner follow:

1. Claim 1 stands rejected under the enablement provision of 35 U.S.C. § 112, first paragraph.
2. Claim 1 stands rejected under 35 U.S.C § 103(a) as unpatentable over the combination of Zhang<sup>3</sup> and Bonjouklian<sup>4</sup>.

We reverse.

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<sup>2</sup> Appellants direct attention to the petition filed concurrently with the Supplemental Appeal Brief (App. Br.) requesting “rejoinder of withdrawn Claims 15-20” (App. Br. 1). This petition was dismissed as untimely (*see* October 1, 2007 Decision on Petition). Accordingly, withdrawn claims 15-20 were not considered in our deliberations.

<sup>3</sup> Xiaoyan Zhang et al., *Up-regulation of phosphatidylinositol 3-kinase in psoriatic lesions*, 112(12) Chinese Medical Journal 1097-1100 (1999).

<sup>4</sup> Bonjouklian et al., US 5,378,725, issued January 3, 1995.

*Enablement:*

ISSUE

Does Appellants' Specification provide an enabling disclosure that is sufficient to allow a person of ordinary skill in this art to practice the claimed invention, which requires the administration of a small organic molecule inhibitor of integrin linked kinase (ILK), without undue experimentation?

FINDINGS OF FACT

FF 1. The Examiner finds that Appellants' Specification provides an enabling disclosure "for the ILK inhibitor compounds of US Patent 6214813, wortmannin, LY294002, and MC-5", but does not provide an enabling disclosure of other small organic molecule ILK inhibitors (Ans. 3).

FF 2. The Examiner finds that the breadth of claim 1 is broad and encompasses the use of any small organic molecule, including "methane, ethane, ethanol, aspirin, etc." (Ans. 4)

FF 3. The Examiner acknowledges that prior to Appellants' filing date "US 6,214,813 and 6,219,447", as well as, Persad<sup>5</sup> described small molecule ILK inhibitors (Ans. 9).

FF 4. The Examiner acknowledges that Appellants' Specification discloses screening methods to identify small molecule ILK inhibitors (Ans. 10).

PRINCIPLES OF LAW

Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. . . . The test is not merely quantitative,

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<sup>5</sup> "Persad et al. (2000) Proc Natl Acad Sci U S A. 97(7):3207-12" (App. Br. 5).

since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.

*In re Wands*, 858 F.2d at 736-37 (citations omitted).

Further, “[t]he specification need not explicitly teach those in the art to make and use the invention; the requirement is satisfied if, given what they already know, the specification teaches those in the art enough that they can make and use the invention without “undue experimentation.” *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1334 (Fed. Cir. 2003):

#### ANALYSIS

The Examiner finds that Appellants’ Specification fails to provide an enabling description of small organic molecule ILK inhibitors that is commensurate in scope with claim 1 (FF 1). In this regard, the Examiner finds that the breadth of claim 1 is broad and encompasses the use of any small organic molecule, including “methane, ethane, ethanol, aspirin, etc.” (FF 2). We are not persuaded.

Appellants contend that “[t]he present application does not claim to have discovered methods or compounds for the inhibition of ILK, but rather utilizes various methods well known in the art for the inhibition of ILK, and applies these methods to the novel use of treating psoriasis” (App. Br. 3-4). In this regard, Appellants contend that “[p]rior to the present invention, small molecule inhibitors of ILK activity as well as methods of utilizing such small molecules to inhibit ILK activity were well known and publicly available” (App. Br. 4). The Examiner acknowledges that small molecule ILK inhibitors were known in the art prior to Appellants’ filing date (FF 3). In addition, the Examiner acknowledges that Appellants’ Specification

discloses screening methods to identify small molecule ILK inhibitors (FF 4; *see also* App. Br. 5).

In sum, we are compelled to agree with Appellants' contention that "the scope of Claim 1 does not encompass *any* small molecule inhibitor, but rather only those small molecules that inhibit ILK, such molecules being a well known class of inhibitors that were routinely used in the art at the time of the present invention" (App. Br. 5).

### CONCLUSION OF LAW

Appellants' Specification provides an enabling disclosure that is sufficient to allow a person of ordinary skill in this art to practice the claimed invention, which requires the administration of a small organic molecule inhibitor of integrin linked kinase (ILK), without undue experimentation. The rejection of claim 1 under the enablement provision of 35 U.S.C. § 112, first paragraph is reversed.

*Obviousness:*

### ISSUE

Does the preponderance of evidence on this record support the Examiner's conclusion of obviousness?

### FINDINGS OF FACT

FF 5. Bonjouklian teaches "that wortmannin is an inhibitor of phosphatidylinositol 3-kinase . . . useful in the treatment of a variety of PI 3-kinase dependent biological processes" (Ans. 6).

FF 6. Bonjouklian does not teach "the use of wortmannin in the treatment of psoriasis" or that it is "an inhibitor of ILK" (Ans. 7).

FF 7. Zhang teaches “that PI 3-kinase is up regulated in psoriatic lesions . . . and that the over-expression of PI 3-kinase may be related to the hyperproliferation of psoriatic keratinocytes” (*id.*).

FF 8. Zhang teaches that “[f]urther studies are required to elucidate” the relationship between PI 3-kinase and the hyperproliferation of psoriatic keratinocytes (Zhang 1099: col. 2, ll. 4-8).

FF 9. The Examiner relies on the disclosure at page 5 of Appellants’ Specification to teach a relationship between ILK and PI 3-kinase (Ans. 7).

#### PRINCIPLES OF LAW

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). Nevertheless, while the analysis under 35 U.S.C. § 103 as set forth in *KSR* allows flexibility in determining whether a claimed invention would have been obvious, it still requires showing that “there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *Id.* at 418.

[P]rior art fails to provide the requisite “reasonable expectation” of success where it teaches merely to pursue a “general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.”

*Medichem S.A. v. Rolabo S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (quoting *In re O’Farrell*, 853 F.2d 894, 903-04 (Fed. Cir. 1988)).

## ANALYSIS

Based on the combined teachings of Bonjouklian and Zhang, the Examiner concludes that “[i]t would have been obvious to [one] of ordinary skill in the art at the time the invention was made to use wortmannin as a small organic molecule inhibitor of ILK in a method of treating psoriasis, as wortmannin was shown to be an inhibitor of PI 3-kinase . . .[which is] up-regulated in psoriatic lesions” (Ans. 7-8). We are not persuaded.

The Examiner recognizes that Bonjouklian fails to teach a method for treating psoriasis (FF 6). Zhang, at best, teaches “that PI(3)-kinase *may* be correlated with hyperproliferation of psoriatic keratinocytes, but that ‘further studies are required to elucidate it’” (App. Br. 11; FF 8). While Zhang identifies what may be a promising field of experimentation, it fails to make up for the deficiencies in Bonjouklian (*see* App. Br. 11). The disclosure relied upon by the Examiner at page 5 of Appellants’ Specification also fails to make up for the deficiency in the combination of Bonjouklian and Zhang (FF 9).

In addition, the Examiner fails to identify a teaching in either Bonjouklian or Zhang of a connection between PI 3-kinase and ILK. The only nexus between PI 3-kinase and ILK identified by the Examiner is derived from Appellants’ Specification (*see* Ans. 7).

In sum, we are compelled to agree with Appellants’ contentions that the evidence relied upon by the Examiner fails to support a *prima facie* case of obviousness (*see* App. Br. 12).



CONCLUSION OF LAW

The preponderance of evidence on this record fails to support the Examiner's conclusion of obviousness. The rejection of claim 1 under 35 U.S.C § 103(a) as unpatentable over the combination of Zhang and Bonjouklian is reversed.

REVERSED

alw

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